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Maria Laura Gennaro

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PATENT DOCKET ADMINISTRATOR
LOWENSTEIN SANDLER PC
65 LIVINGSTON AVENUE
ROSELAND, NJ 07068

EXAMINER

SWARTZ, RODNEY P

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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/009,383
Filing Date: March 04, 2002
Appellant(s): GENNARO, MARIA LAURA

Lisa K. Schroeder
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 2 July 2009 appealing from the Office action mailed 4 February, 2009.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

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(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 3-7, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reed et al (WO98/16645, 23 April 1998).

The claims are drawn to an isolated DNA molecule consisting of a DNA sequence encoding polypeptide MTBN4 or shortened lengths thereof, vectors and cells comprising the DNA.

Instant polypeptide MTBN4 is SEQ ID NO:4. A sequence search for SEQ ID NO:4 indicates that sequence is identical to SEQ ID NO:110 of WO98/16645. Reed et al not only teach the amino acid sequence of MTBN4, but also teach an isolated DNA comprising the DNA sequence encoding the polypeptide, i.e, a fragment of SEQ. ID. No:109 (Example 3, page 38, lines 22-27). Given that the protein sequence was known, one of ordinary skill in the art would instantly envision a polynucleotide sequence consisting of a DNA encoding said sequence and that said DNA sequence is obvious. Furthermore, it would have been obvious to one of ordinary skill in the art to place the sequence into a vector, transform a host cell with that vector, and to admix said vector with a pharmaceutically acceptable diluent or filler as taught by Reed et al for the other DNA sequences in the document (page 39, line 18 to page 45, line 1; claims 5-8, 40-47).

(10) Response to Argument

Appellant argues that Reed et al does not teach or fairly suggest the selection of a DNA sequence encoding MTBN4 for combination with at least one additional DNA sequence encoding a polypeptide that is encoded by *M. tuberculosis*, but that is not encoded by the genome of the BCG strain of *M. bovis* to yield vectors, cells, and composition put forth in the instant claims.

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While Reed et al does make a general reference to using polypeptides in combination with each other, they do nothing to teach or suggest that one of ordinary skill in the art employ the particular combination of the present invention, i.e., combining a sequence encoding MTBN4 with the sequence of another polypeptide that is encoded by *M. tuberculosis* but not the BCG strain of *M. bovis*. Appellant argues that the DNA sequence combination of the pending claims yield an additional advantage over the polypeptide combination contemplated by Reed et al. Appellant argues that Reed et al do not teach or fairly suggest the selection of a DNA sequence encoding MTBN4 for combination with additional elements to yield the vectors, cells, and composition of the instant application.

The examiner has considered appellant's arguments, but does not find them persuasive because the teachings of Reed et al would have suggested one of ordinary skill in the art to place the claimed sequences into a vector, transform a host cell with that vector, and to include at least one additional DNA sequence (page 39, line 18 to page 45, line; claims 5-8, 40-47). In addition, Reed et al teach polypeptides and their DNA sequences which are unique to *M. tuberculosis* (page 38, lines 3-30).

Thus, it would have been obvious to one of ordinary skill in the art to place the sequences taught by Reed et al which are unique to *M. tuberculosis* into a vector, transform a host cell with that vector, and produce composition thereof, using the elements and techniques taught by Reed et al.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

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Respectfully submitted,

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

Conferees:

Robert Mondesi, SPE, Art Unit 1645

/Robert B Mondesi/

Supervisory Patent Examiner, Art Unit 1645

Jeffrey Stucker, SPE, Art Unit 1649

/Jeffrey Stucker/

Supervisory Patent Examiner, Art Unit 1649